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Pesticide Fact Sheet Number 123: Propham

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Office of Pesticides and Toxic Substances
Office of Pesticide Programs (TS-766C)
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EPA

Pesticide Fact Sheet

PB87-191938

Name of Chemical: Propham (isopropyl carbanilate)
Reason for Issuance: Registration Standard
Date Issued: MAR 31 1987
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1. DESCRIPTION OF CHEMICAL

Generic Name:	isopropyl carbanilate
Common Name:	Propham
Trade Name:	Chem-Hoe®, Birgin, Triherbide
EPA Shaughnessy Code:	047601
Chemical Abstracts Service (CAS) Number:	122-42-9
Year of Initial Registration:	1967
Pesticide Type:	Herbicide
Chemical Family:	Carbamate
U.S. and Foreign Producers:	Propham is produced in the Federal Republic of Germany by Bayer AG; in the Netherlands by Pennwalt Holland B.V.; and in the United States by PPG Industries, Inc.

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US Environmental Protection Agency
Office of Pesticide Programs
Registration Division, TS-767C
401 M Street, S.W.
Washington, D.C. 20460

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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors
Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, Science Findings

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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2. USE PATTERNS AND FORMULATIONS

Application sites: Propham is registered for use on terrestrial food crops such as sugar beets, lettuce, alfalfa, clover, peas, lentils, safflower, and spinach and nonfood crops including established grasses grown for seed, flax and established perennial grass and fallow land. Most propham usage is confined to the western United States.

Percent of pesticide applied to particular crops: The significant uses of propham are in forage legumes (alfalfa and clover), sugar beets, and lettuce, which account for nearly 100 percent of its use.

Types and methods of application: Propham may be applied preplant, preemergence, and postemergence by ground or aerial equipment. The flowable concentrate formulation may also be applied in irrigation water or through center pivot sprinkler irrigation systems for certain uses. In limited areas, propham may be tank mixed with other herbicides for application to lettuce, spinach grown for seed, and fallow land to be planted to wheat. Also, since herbicidal action is mainly through the roots, soil surface applications must be moved into the root zone of weeds by rainfall or irrigation soon after application.

Application rates: The flowable concentrate is applied at the rate of 1 to 6 pounds of a.i. per acre depending on the soil, site, and pest controlled. The granular formulation is applied at the rate of 4.1 to 5.25 pounds a.i. per acre, depending on soil type.

Types of formulations: Flowable concentrations (43 and 31 percent active ingredient) and granular (15 percent active ingredient) formulations.

Usual carrier: Water

3. SCIENCE FINDINGS

Summary science statement: Propham has low acute oral and dermal toxicity and is classified in toxicity Category III.* Additional toxicological assessment is not possible at this time due to insufficient data. Based on the available information, application of propham on proposed use sites is unlikely to result in environmental hazard to nontarget organisms other than plants because of its low toxicity to wildlife. Additional data are required before the environmental fate, including potential to contaminate ground water, of propham can be assessed.

Chemical characteristics:

Physical state:	Solid
Color:	Tan to light grey
Odor:	Faint amine-like odor
Melting point:	87 to 88 °C
Octanol/water partition coefficient:	445 ± 17 over a propham concentration range of 0.5 to 100 ppm (pure active ingredient)

Toxicological characteristics: Only acute oral and dermal toxicity studies are available. Other studies are required.

Acute Oral Toxicity :	Category III 2360 ± 118 mg/kg (female rats) 3000 ± 232 mg/kg (male rats)
Acute Dermal Toxicity:	Category III Greater than 3000 mg/kg (rabbits)

Major route of exposure: Dermal.

Subchronic toxicological results: Only one supplemental study, a 90-day feeding study in rats, is available. In that study the no observed effect level (NOEL) was 250 ppm (approximately 12.5 mg/kg/day). Additional studies are required.

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* Refer to 40 CFR 162.10 for a discussion of the toxicity categories.

Chronic and Developmental toxicological results: The only acceptable study available is a rat teratology study. In that study, NOEL's for maternal toxicity and developmental effects were 375.8 and 37.6 mg/kg, respectively. Additional chronic and developmental studies are required.

Physiological characteristics:

Foliar absorption - Intact leaf surfaces do not absorb an appreciable amount of propham.

Translocation - Propham is absorbed by roots and a portion is translocated via the apoplastic system to the shoots and the balance metabolized in the roots. That which reaches the shoots may be metabolized or volatilized.

Mechanism of pesticide action - Propham is a mitotic poison that kills roots by inhibiting cell division. Propham produced rapid inhibition of cell activity and contraction of chromosomes, probably at all stages of cell division.

Environmental characteristics: With the exception of an aerobic soil metabolism study, available data are insufficient to fully assess the environmental fate of, and the exposure of humans and nontarget organisms to, propham. Data are required.

Under aerobic conditions, propham degraded with a half-life of 7 to 14 days in sandy loam soil. Two degradates were isolated from the soil but not identified.

Ecological characteristics:

Hazards to fish and wildlife - Propham has a very low acute oral toxicity to birds, it is slightly toxic to coldwater and warmwater fishes and moderately toxic to freshwater invertebrates. The following are toxicity levels from available data:

Avian oral toxicity	:	> 2000 ppm; additional data requested
Avian dietary toxicity	:	Data required

Freshwater fish toxicity
(Bluegill) : 29 to 34.8 ppm
(Rainbow trout) : 23.5 to 38 ppm

Freshwater invertebrate
toxicity (Daphnia pulex) : 8 ppm

Potential problems related to endangered species:

None.

Tolerance assessment:

List of crops and tolerances - Interim tolerances are established for residues of propham in or on raw agricultural commodities as follows (40 CFR 180.319):

Commodities	Parts Per Million
Hay of alfalfa, clover, and grass	5.0
Alfalfa, clover, and grass	2.0
Flaxseed, lentils, lettuce, peas, safflower seed, spinach, and sugar beets (roots and tops)	0.1
Eggs; milk; and the meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep	0.05

Results of tolerance assessment: The Provisional Limiting Dose (PLD) for propham is 0.0125 mg/kg. This PLD is based on a 3-month rat feeding study, with a NOEL of 12.5 mg/kg/day (approximate conversion from 250 ppm), and applying a safety factor of 1000. This is equivalent to a PLD of 0.75 mg/day for a 60 kg individual. The Theoretical Maximum Residue Concentration (TMRC), based on the total tolerances listed and a daily food intake of 1.5 kg, is 0.043 mg/day, utilizing 5.7 percent of the PLD.

4. SUMMARY OF REGULATORY POSITION AND RATIONALE

1. The Agency is not initiating a Special Review of propham at this time.

   Rationale: Since available data are limited, the Agency is not yet able to make a determination as to whether any of the criteria specified in 40 CFR 154.7 have been met or exceeded.

2. No new significant* tolerances will be considered until the Agency has received data sufficient to thoroughly evaluate propham.

   Rationale: The toxicology data base on propham is not sufficient to consider establishment of new significant tolerances. In addition, the metabolism of propham in plants and animals is not adequately defined.

3. The Agency is requiring the following residue chemistry data: plant and animal metabolism and storage stability studies; residue studies for sugar beet roots, sugar beet tops, lettuce, spinach, peas (succulent and dry), lentils, grass forage, grass hay, alfalfa forage, alfalfa hay, flaxseed, and safflower seed; and processing studies to determine residues in dried pulp, molasses, and refined sugar from sugar beets; meal and hulls from flaxseed; and meal and oil from safflower seed. Petitions for food/feed additive tolerances, will be required if residues concentrate.

   Rationale: Adequate data are not available to assess the adequacy of existing tolerances or to ascertain the need for food/feed additive tolerances in processed commodities.

4. The Agency is requiring the registrant to: (i) propose appropriate Pre Grazing Intervals/Pre Harvest Intervals (PGIs/PHIs) for clover, lettuce, spinach, and sugar beets; (ii) designate propham registration for grasses as either pasture or rangeland use, and propose an appropriate PGI and PHI if pasture use is designated; and (iii) propose tolerances and provide supporting residue data or propose feeding restrictions for pea vines, pea vine hay, lentil forage, lentil hay, and flax straw. These proposals must be submitted with the revised labeling and in accordance with the timeframe required by this document for submittal of revised labeling or the Agency will impose appropriate feeding restrictions. (refer to chapter IV, D of this document, Required Labeling)

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* Significant new use is defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will consider as significant an increase in the Theoretical Maximum Residue Contribution of greater than 1 percent.

Rationale: Data are either unavailable or do not support the existing PGI/PHI or do not demonstrate that no PGI/PHI is needed for the cited crops. Adequate information is not available regarding the use for grasses and this use must be clarified and fully supported. There is currently no protective mechanism (either tolerances or feeding restrictions) to prevent excessive residues of propham in pea vines, pea vine hay, lentil forage, lentil hay, and flax straw.

5. The Agency is requiring the registrant to propose that the interim tolerances under 40 CFR 180.319 be converted to "permanent" tolerances under a separate paragraph of the published tolerance expressions at the same or, if necessary, different concentrations and provide the requested residue data to support these tolerances.

   In addition, the registrant must propose the following changes to commodity definitions in the tolerance statement: (i) "alfalfa" to "alfalfa forage"; (ii) "clover" to "clover forage"; (iii) "grass" to "grass forage"; and (iv) "peas" to "peas (succulent and dry)".

   Rationale: Interim tolerances were established when petitions for tolerances for negligible residues were pending. Since available data do not support the interim tolerances, as established, permanent tolerances can not be set based on currently available data. Therefore, when data are submitted in accordance with this document, the registrant must request conversion to permanent tolerances, and revise the commodity definitions to conform to current terminology or the Agency will propose revocation of the tolerances.

6. The Agency is requiring additional toxicological data, as set forth in Table A of this document to assess the toxicity of propham. Certain Acute, Subchronic, and Chronic testing is required.

   Rationale: These data are normally required under 40 CFR 158 for products with propham's use patterns. Existing data are insufficient to permit the Agency to thoroughly assess the toxicity of propham.

7. The Agency is requiring additional ecological effects data (see Table A).

   Rationale: Available data are insufficient or lacking to fully assess the hazard from propham use to the avian population.

8. The Agency is requiring environmental fate data as set forth in Table A.

   Rationale: Because the requirements have not been fully satisfied, available data are insufficient to fully assess the environmental fate of propham. The leaching data that is available indicate a potential for ground water contamination. Hydrolysis, photodegradation, metabolism, leaching, dissipation, and accumulation studies are required.

9. The Agency is not establishing a reentry interval at this time.

   Rationale: Data adequate to assess the need for a reentry interval for field workers are not available. Once data are received and evaluated, the Agency will determine the need for such an interval. An interim interval is not required because of the low acute toxicity demonstrated by the available data.

10. The Agency is requiring environmental precautionary labeling.

    Rationale: The Agency's regulations (40 CFR 162.10) require environmental hazards labeling. Updated labeling consistent with 162.10 is required. Additional required labeling statements to protect wetlands are specified in the registration standard Section D.3.

11. The Agency has identified certain data that will receive priority review when submitted.

    Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and /or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

    §158.130 Environmental Fate

    161-1 Hydrolysis
    161-2,3 Photodegradation
    163-1 Leaching and Adsorption/Desorption
    164-1 Soil Dissipation (Field)
    165-1 Rotational Crops (confined)

12. While data gaps are being filled, registered manufacturing-use products (MPs) and end-use products (EPs) containing propham as the sole active ingredient may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

    Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA section 3(c)(2)(B) and 3(c)(7)). The limited, available data do not indicate any immediate, serious concern.

    Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

Unique warning statements required on labels:

a. Manufacturing-Use Products

    "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or regional office of EPA."

b. End-Use Products

    "Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes."

5. SUMMARY OF MAJOR DATA GAPS

Study	Due Date*
Toxicology:	
Acute Testing	9 months
90-Day Feeding (rodent)	15 months
90-Day Feeding (nonrodent)	18 months
21-Day Dermal	12 months
Chronic Toxicity (rodent and nonrodent)	50 months

Oncogenicity (rat and mouse)	50 months
Teratogenicity (rabbit)	15 months
Reproduction	39 months
Gene Mutation	9 months
Chromosomal Aberration	12 months
Other Mechanisms of Mutagenicity	12 months
General Metabolism	24 months

Residue chemistry:

Metabolism	18 months
Storage stability	15 months
Residue studies	18 months
Processed Commodity Studies	24 months

Environmental fate:

Hydrolysis	9 months
Photodegradation (water, soil)	9 months
Anaerobic Soil	27 months
Mobility (leaching and adsorption/desorption)	12 months
Soil dissipation	27 months
Rotational crops	39 months
Fish accumulation	12 months
Reentry	27 months

Ecological effects:

Avian oral and dietary	9 months

6. CONTACT PERSON AT EPA

Robert J. Taylor
Product Manager 25
Office of Pesticide Programs
Registration Division (TS-767C)
Environmental Protection Agency
401 M Street SW.
Washington, DC 20460
Telephone: (703) 557-1800

DISCLAIMER: The information presented in this Pesticide Fact Sheet is for informational purposes only and may not be used to fulfill data requirements for pesticide registration and reregistration.

*Indicates months due after issuance of Standard or, in some cases of residue chemistry data, after first planting season after issuance of Standard. Refer to Standard for more information.